

U.S. Patent Application Serial No. 10/580,415  
Response filed December 1, 2008  
Reply to OA dated September 3, 2008

**REMARKS**

Claim 1 is pending in this application. The Abstract is amended herein. Entry of this amendment and reconsideration of the rejections are respectfully requested.

**Telephone Interview on Monday, September 22, 2008**

Applicant's agent, Daniel Geselowitz, conducted a telephone interview with Examiner Chunduru on Monday, September 22, 2008. The content of that interview is detailed below.

**The specification is objected because of informalities.** (Office action paragraph no. 3)

The Examiner states that there are no sequence identifiers (SEQ ID NOS) in the abstract, and again states that the application does not contain a Sequence Listing in paper or computer readable form.

Applicant's agent contacted the Examiner on Monday, September 22, 2008, regarding the latter issue.

Applicant's agent noted that, as stated in the Amendment filed on May 12, 2008, the Sequence Listing was filed on May 22, 2006. The Examiner explained that the inclusion of the comment regarding the missing sequence listing was a mistake.

Regarding the issue of sequence identifiers in the abstract, Applicant here amends the abstract to include the sequence identifiers, as requested. Applicant submits, however, that this amendment is not necessary, since the abstract is not actually part of the specification, and the purpose of the abstract is to "enable the USPTO and the public generally to determine quickly from a cursory

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inspection the nature and *gist* of the technical disclosure," that is, without reference to the specification (including sequence listing). See MPEP 608.01(b).

**Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Cech et al. (US 6,475,789).** (Office action paragraph no. 4)

The rejection of claim 1 is respectfully traversed, and reconsideration is requested.

The Examiner cites Cech at column 4, lines 6-27, and column 79, lines 12-25, for a step of obtaining a sample containing RNA only, in particular citing column 80, lines 22-49, as disclosing the step of selectively extracting the RNA.

The Examiner also cites Cech as disclosing a reverse transcription reaction at column 80, lines 37-47, and column 105, lines 25-38, and states that the reference discloses a PCR step using SYBR green I and the primers LT5 and LT6, corresponding to SEQ ID NOS: 1 and 2 of claim 1 (citing column 105, lines 39-57, and Table 2).

Reviewing the reference, Applicant notes that Cech generally discloses method related to hTRT, and the reference states that these may be useful in diagnosis of human diseases (abstract). At column 4, line 6, the reference discloses a method for diagnosing cancer involving detecting an hTRT gene product in a patient sample. The disclosures at column 4, lines 6-27, and column 79, lines 12-25, cited by the Examiner, do not disclose obtaining an "RNA only" sample. Only in column 80, lines 31-36, does the reference disclose "one embodiment" involving guanidinium-phenol-chloroform extraction and oligo-dT column chromatography, which would result in an "RNA only" sample.

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Regarding the second process in claim 1, the Examiner cites column 80, lines 37-47.

Applicant notes that this portion of the reference reads: "In alternative embodiments, it is not necessary to isolate nucleic acids (e.g., total or polyA+ RNA) from the biological sample prior to carrying out amplifications ...." This portion of the reference cannot anticipate claim 1.

More significantly, the Examiner relies on the citation of column 105, lines 25-38, of Cech, for the disclosure of primers LT5 and LT6. The cited lines are a portion of Example 2 of the reference, and disclose RT-PCR for hTRT on RNA derived from 12 sources, which appear to be various human cell lines. Column 105, line 40, states that the primers were LT5 and LT6 of Table 2 (see column 24). LT6 matches SEQ ID NO: 2.

However, LT5 is CGGCCCGAGTGTCTGGAGCAA, which **does not match SEQ ID NO: 1**. LT5 differs in having the nucleotides 4-5 be "CC," while in SEQ ID NO: 1, these are "AA." **The use of LT6 in Cech cannot anticipate the use of SEQ ID NO: 1 in claim 1.**

Moreover, regarding the fluorescent dye in claim 1, the Examiner cites the use of SYBR Green I in Cech at column 105, lines 39-57. However, this portion of the reference (line 52) specifically states: "Reaction products were resolved on an 8% polyacrylamide gel stained with SYBR Green ...." That is, SYBR Green is used only for gel staining, and was **not present during the PCR reaction** in the reference. Claim 1, however, requires "a PCR reaction step in the presence of a fluorescent dye."

Therefore, the disclosure of Cech clearly differs from claim 1 in two regards:

- 1) Cech does **not** disclose use of the primer of SEQ ID NO: 1, since Cech's LT5 does not have the same sequence as SEQ ID NO: 1.

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2) Cech does **not** disclose conducting a PCR reaction in the presence of a fluorescent dye.

Claim 1 is therefore clearly not anticipated by Cech et al. (US 6,475,789).

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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